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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,499	12/29/2003	Richard C. Gunderson	1001.1733101	1209

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CROMPTON, SEAGER & TUFTE, LLC  
1221 NICOLLET AVENUE  
SUITE 800  
MINNEAPOLIS, MN 55403-2420

EXAMINER
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STIGELL, THEODORE J

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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07/02/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/749,499

Applicant(s)

GUNDERSON, RICHARD C.

Examiner

Theodore J. Stigell

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17-19 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17-19 and 22-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Response to Amendment***

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 12-13, 15, 23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Mueller, Jr. ('220). Mueller, Jr. discloses a medical device comprising a tubular member (16), a radiopaque marker band (10) with an inner surface (not referenced), an outer surface (not referenced) and an opening (12), and an outer layer that at least partially fills the opening (19). (See Figure 2)

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

*Claims 2-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller, Jr. ('220) in view of Nutting et al. ('489).*

Mueller, Jr. discloses a medical device comprising a tubular member (16); a radiopaque marker band (10) with an inner surface (not referenced), an outer surface (not referenced) and an opening (12); and an outer layer (19). (See Figure 2)

Mueller, Jr. fails to disclose openings that are defined by circles, ovals, or a plurality of slots in different configurations.

Nutting et al. teaches a marker band with a circular hole and with two slots. In one configuration the slots are aligned on either side of the marker band. In another configuration the slots are offset on either side of the marker band. (See Figure 8-10)

Nutting et al. fails to specifically disclose an oval opening.

The only difference between the prior art and the claims was a recitation of an oval shape of the claimed device and a device having the claimed oval shape would not perform differently than the prior art device, therefore the claimed device was not patentably distinct from the prior art.

Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Mueller, Jr. with the teachings of Nutting et al. to provide a marker band with a variety of opening configurations.

*Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller, Jr. ('220) in view of McBroom et al. ('108).*

Mueller, Jr. discloses a medical device comprising a tubular member (16); a radiopaque marker band (10) with an inner surface (not referenced), an outer surface (not referenced) and an opening (12); and an outer layer (19). (See Figure 2)

Mueller, Jr. fails to disclose openings that are defined by slits in a proximal and distal region of the marker band.

McBroom et al. discloses a marker band comprising a top surface, a bottom surface and vertical perforations extended from the top surface to the bottom surface. (See Figure 6)

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the disclosure of Mueller, Jr. with the teachings of McBroom et al. to provide a marker band with a plurality of slits in the proximal and distal regions of the band.

*Claim 11* is rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller, Jr. ('220) in view of Eidenschink et al. ('734).

Mueller, Jr. discloses a medical device comprising a tubular member (16); a radiopaque marker band (10) with an inner surface (not referenced), an outer surface (not referenced) and an opening (12); and an outer layer (19). (See Figure 2)

Mueller, Jr. fails to disclose an outer surface defined by a fluorocarbon polymer.

Eidenschink et al. teaches a catheter defined by a fluorocarbon polymer such as polytetrafluoroethylene. (See Column 4 Lines 44-53)

It is well known in the art of catheter construction to use a fluorocarbon polymer as illustrated by Eidenschink et al. Thus, it would have been obvious to one of ordinary skill

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in the art at the time of the invention to use a fluorocarbon to manufacture the medical device of Mueller, Jr.

*Claim 14* is rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller, Jr. ('220) in view of Eidenschink et al. ('734) further in view of Hopkins ('489).

Mueller, Jr. discloses a medical device comprising a tubular member (16); a radiopaque marker band (10) with an inner surface (not referenced), an outer surface (not referenced) and an opening (12); and an outer layer (19). (See Figure 2)

Mueller, Jr. fails to disclose an outer surface defined by a fluorocarbon polymer.

Eidenschink et al. teaches a catheter defined by a fluorocarbon polymer such as polytetrafluoroethylene. (See Column 4 Lines 44-53)

It is well known in the art of catheter construction to use a fluorocarbon polymer as illustrated by Eidenschink et al. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a fluorocarbon to manufacture the medical device of Mueller, Jr.

Eidenschink et al. fails to disclose a core member that is a guidewire.

Hopkins teaches placing a marker band on a guidewire. (See Column 1 Lines 17-20)

Thus, it would have been obvious at the time of the invention to one of ordinary skill in the art to modify the disclosure of Mueller, Jr. with the teachings of Hopkins such that the marker band is disposed on a guidewire.

*Claim 24* is rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller, Jr. ('220) in view of Nebergall et al. ('095).

Mueller, Jr. discloses a medical device comprising a tubular member (16); a radiopaque marker band (10) with an inner surface (not referenced), an outer surface (not referenced) and an opening (12); and an outer layer (19). (See Figure 2)

Mueller, Jr. fails to disclose an outer layer comprising multiple segments.

Nebergall et al. teaches a band disposed over an inner tubular member and outer layer with multiple segments extending over the band. (See Figure 4)

*Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nutting et al. ('489) in view of McBroom et al. ('108).*

Nutting et al. discloses a marker band with a circular hole and with two slots. In one configuration the slots are aligned on either side of the marker band. In another configuration the slots are offset on either side of the marker band. (See Figure 8-10)

Nutting et al. fails to disclose one or more slits in the proximal or distal end regions of the marker band.

McBroom et al. teaches a marker band comprising slits in the proximal and distal end regions of the marker band. (See Figure 6 and 7)

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Nutting et al. with the teachings of McBroom et al. to provide a marker band with one or more slits in the proximal and distal end regions.

*Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ye et al. (US 2002/0156460) in view of Nutting et al. ('489).*

Ye discloses a method of securing a marker band to a balloon catheter comprising the steps of: providing a catheter (28), disposing a marker band (40) over the catheter, and disposing a coating (48) over the marker band.

Ye fails to disclose a marker band comprising slots.

Nutting et al. teaches a marker band with a circular hole and with two slots. In one configuration the slots are aligned on either side of the marker band. In another configuration the slots are offset on either side of the marker band. (See Figure 8-10)

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the disclosure of Ye with the teachings of Nutting et al. to provide a method of securing a marker band with openings to a medical device.

### ***Response to Arguments***

Applicant's arguments filed 12/07/2006 have been fully considered but they are not persuasive.

In response to the Applicant's argument that Mueller does not disclose an outer layer that fills the opening, the Examiner respectfully disagrees. The distal end (19) of the outer layer at least partially fills the opening (12).

In response to the Applicant's argument that McBroom does not disclose the slits in the proximal and distal ends, the Examiner respectfully disagrees. It is the Examiner's position that Figure 6 shows slits in the proximal and distal ends.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP



§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

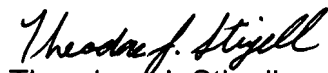
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Theodore J. Stigell

  
NICHOLAS D. LUCCHESI  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700